DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 12, 2015

Fournitures Hospitalieres Industrie
Ms. Patricia Donnard
Regulatory Affairs Manager
6 rue Nobel- ZI de Kernevez
29000 Quimper
France

Re: K150471
Trade/Device Name: CalcaNail Orthopedic Arthrodesis Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: February 14, 2015
Received: February 23, 2015

Dear Ms. Donnard:

This letter corrects our substantially equivalent letter of May 22, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150471

Device Name
CalcaNail Orthopedic Arthrodesis Nail

Indications for Use *(Describe)*
The CalcaNail Orthopedic Arthrodesis Nail is intended for subtalar arthrodesis in the treatment of patients with:
- Comminuted fractures of the calcaneus
- Post-traumatic osteoarthritis and/or poor function resulting from calcaneal fracture sequelae
- Osteoarthritis of the posterior subtalar joint, or
- Valgus flatfoot deformities

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
CalcaNail Orthopedic Arthrodesis Nail
K150471

May 20, 2015

1. Submitter

Fournitures Hospitalieres Industrie (FHI)
ZI de Kernevez – 6 rue Nobel
29000 QUIMPER – France
Establishment Registration # 3003898228
Owner/Operator # 9025586

Contacts:
Patricia Donnard
Regulatory Affairs Manager
Email: p.donnard@fh-industrie.com

Or

Naoual Rahimi
Regulatory Affairs Representative
Email: n.rahimi@fh-industrie.com

Tel number: +33.2.98.55.68.95
Fax: +33.2.98.53.42.13

2. Name of Device

Proprietary Name: CalcaNail Orthopedic Arthrodesis Nail

Common Name: Orthopedic Nail

Device Classification: Intramedullary Fixation Rod

Product Code: 87 HSB (Rod, Fixation, Intramedullary and Accessories)

These devices have been placed in Class II as per 21 CFR Regulation Number 888.3020 and assigned the Product Code 87 HSB.

3. Predicate Devices

The components of the CalcaNail Orthopedic Nail are substantially equivalent to the following legally marketed devices:

- Synthes Calcaneal Locking Plate K991407
- FHI Cannulated Screws K070617
- NewDeal Panta Nail K091788

This statement is based on the similarity of the subject device to the predicate devices in one or more of intended use, materials, design and principles of operation.

4. Device Description

The CalcaNail is orthopaedic nail for the repair of articular fractures of the calcaneus. The device consists of an orthopedic titanium 12 mm nail available in 3 lengths (65 mm, 75 mm and 85 mm) for subtalar arthrodesis. The system also includes a series of 5 mm cannulated screws for fixation available in 17 lengths (24 mm – 80 mm)

5. Intended Use

The CalcaNail Orthopedic Arthrodesis Nail is intended for subtalar arthrodesis in the treatment of patients with:

- Comminuted fractures of the calcaneus
- Post-traumatic osteoarthritis and/or poor function resulting from calcaneal fracture sequelae
- Osteoarthritis of the posterior subtalar joint, or
- Valgus flatfoot deformities

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6. Comparison to Predicate Devices

The CalcaNail System has been carefully compared to legally marketed devices with respect to intended use and safety and effectiveness. The Synthes calcaneal locking plate K991407, FHI cannulated screws K070617, NewDeal Panta Nail K091788 are all indicated for use in the foot, ankle and the calcaneus with the nails and screws including subtalar arthrodesis. All devices are manufactured from titanium and/or stainless steel and are available with delivery instruments for proper use.

Seven pairs of (total of 14) enzymatically corroded human calcaneal and talar bones were fixed either by the CalcaNail Orthopedic Screw or Synthes locking plate (K991407) for biomechanical testing. The results of this published testing showed that the primary stability at the chosen experimental set-up of a standardized calcaneal fracture was better with the CalcaNail than with the standard Synthes calcaneal locking plate.

Engineering simulation was used to compare the moments of inertia of the smallest cross-sections of the CalcaNail nail comparing this to the currently marketed FHI cannulated screws (K070617). The analysis performed demonstrated the CalcaNail provided much greater rigidity than the cannulated screws used routinely in rear foot deformity surgery.

7. Summary of Substantial Equivalence

Based on the descriptive information and analysis provided FH Industrie has determined that the CalcaNail Arthrodesis Nail is substantially equivalent to the predicate devices presented. The bench testing and device description confirms that the subject CalcaNail demonstrate no new issues of safety or effectiveness in treating old and recent fractures of the heel bone joint, and hind foot deformity surgery such as arthrodesis.